UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IRA BRIEF and CATHIE BRIEF, husband and wife, Plaintiffs, v. IDELLE LABS, LTD. and JOHN DOE 1 through JOHN DOE 75 (fictitious), Defendants.	Civil Action No. 2:22-cv-05085-WJM-LDW **Hon. William J. Martini** **Oral Argument Requested** **Motion Date: August 21, 2023** *Document electronically filed*

DEFENDANT'S REPLY MEMORANDUM OF LAW IN RESPONSE TO PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION TO DISMISS SECOND AMENDED COMPLAINT

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INTRODUCTION

Defendant Idelle Labs, Ltd. ("Idelle Labs" or "Defendant") moved to dismiss ("Motion" or "Mot.") the Second Amended Complaint (the "SAC" or "Complaint") with prejudice because Plaintiffs have not cured the defects the Court recognized in their First Amended Complaint (the "FAC") and have shown they cannot do so.

To state a viable claim under the NJPLA,[1] a plaintiff must allege facts that plausibly show the product at issue was defective (in this case either a design defect or a failure to warn). Even if a plaintiff can plausibly allege a defect, the plaintiff also must allege facts that plausibly show such defect caused his alleged injury.

As explained in Defendant's Motion, supported by this Court's prior dismissal order and other authoritative case law, Plaintiffs have not met the pleading requirements of the NJPLA: they have not plausibly alleged (i) the existence of a design defect or a failure to warn nor (ii) that any such defect proximally caused Mr. Brief's AML. In their Opposition (ECF No. 42 or "Opp."), Plaintiffs respond by reiterating the allegations in their SAC relating to testing of a single batch of the Products, but they do not meaningfully address the case law that clearly establishes Plaintiffs' failure to meet their pleading burden. As such, Defendant's Motion should be granted, and Plaintiffs' Complaint should be dismissed with prejudice.

ARGUMENT

I. PLAINTIFFS HAVE NOT PLAUSIBLY ALLEGED THAT ANY ALLEGED DEFECT CAUSED THEIR INJURY.

The SAC was unclear as to Plaintiffs' theory of causation: it was left unsaid whether they contend that Mr. Brief's AML was caused by alleged exposure to benzene from his use of one or

[1] Capitalized terms used, but not defined, herein have the meaning ascribed to such terms in Defendant's Memorandum of Law in Support of Motion to Dismiss Plaintiffs' Second Amended Complaint. *See* ECF No. 39-1.

more canisters of the Products from lot 20280, or whether they contend that his AML was caused by alleged exposure to benzene from use of the Products from 1985 to 2022. *See* SAC ¶¶ 33-40; 60-62. Plaintiffs' Opposition makes their theory clear: they argue that Mr. Brief's AML was caused by alleged exposure to benzene from his use of the Products from 1985 to 2022. *See* Opp. at 7-8. The question, then—setting aside for now whether Plaintiffs have plausibly alleged a "defect" under the NJPLA—is whether Plaintiffs have plausibly alleged that Mr. Brief was exposed to benzene at sufficiently high concentrations and over a sufficiently long period of time to cause his AML. They fail to do so.

As to whether Plaintiffs have alleged exposure to benzene in the Products over a sufficiently long period of time, even assuming *arguendo* that Plaintiffs have plausibly alleged that the Products in lot 20280 contained benzene, they have not plausibly alleged that *all* of the Products Mr. Brief used – dating back over a period of nearly 40 years – contained benzene. This Court already held that the alleged testing of three recent batches of the Products does not lead to a plausible inference that all lots contained benzene. *See* ECF No. 30 at 3; *see also Rooney v. Procter & Gamble Co.*, 2023 WL 1419870, at *4 (E.D. La. Jan. 31, 2023) ("That two batches of the kind of antiperspirant product Rooney used allegedly contained benzene does not render plausible plaintiffs' assertion that Rooney herself was exposed to benzene."); *Huertas v. Bayer U.S., LLC*, 2023 WL 3773139, at *10 (D.N.J. May 23, 2023) ("The Tested Product lots do not match any of the lot numbers that individual Plaintiffs purchased. . . . Tests performed on other batches of similar products cannot translate to the assumption that all of the Products at issue here contained benzene, and/or contained excessive levels of such."). If testing of three lots does not lead to a plausible inference of broader contamination, certainly testing of a fourth recent lot is no different. Moreover, all of the lots from which samples allegedly were tested, both by Valisure

and by Plaintiffs, bore expiration dates spanning (and therefore were produced within) a period of just 8 months.[2] It is not reasonable to extrapolate testing results of samples from an 8-month period to nearly 40 years of product sales. Plaintiffs have not alleged facts to establish that exposure over one month (the average length of time Mr. Brief alleges it took him to use one canister of the Products), *see* SAC ¶ 62, or over eight months (the full spread of time in production date for all allegedly tested Products) would be sufficient to develop AML, and their failure to plausibly allege decades of product contamination is fatal to their claims.[3]

As to whether Plaintiffs have sufficiently alleged exposure to benzene at sufficiently high levels to cause AML, Plaintiffs repeat their argument comparing alleged independent test results to an FDA regulatory threshold of 2 PPM, but do not address Defendant's explanation that a conservative regulatory threshold does not establish the dose at which AML plausibly can develop. *See* Mot. at 8-9. As Defendants noted in their Motion, Plaintiffs have not alleged what PPM level

[2] Plaintiffs allege they tested Product bearing lot number 20280 and that Valisure tested Product from lots 21099, 21172, and 21175. SAC ¶¶ 19; 33-39. The expiration dates (and therefore manufacturing dates) of these Products spanned 8 months – expiring between September 2022 and May 2023. SAC ¶ 60; Request for Judicial Notice ("RJN"), ECF No. 40-8 at 12-13 (hereinafter the "Valisure Report"). Plaintiffs argue that this spread in lot numbers raises a plausible inference that all lot numbers **preceding** 20280 were also contaminated with benzene. *See* Opp. at 5-6. The basis for this assumption is baffling: no lots under 20280 were allegedly tested. Their argument is akin to saying "I was eating dinner at 7:30 pm and I was eating dinner at 8:00 pm, so therefore I have been eating dinner since dawn." Their flawed logic does not give rise to a plausible inference of decades of product contamination.

[3] Beyond the testing allegations, the only other argument Plaintiffs raise in their Opposition is that Defendant's voluntary recall provides a plausible inference of the scope of the defect. Opp. at 4-5, 7-8. Plaintiffs, however, do not address this Court's ruling that "the existence of a voluntary recall does not prove a defect," nor do they respond to Defendant's argument that, if a voluntary recall cannot prove the existence of a defect, then it axiomatically cannot prove the scope of that defect. *See* ECF No. 30 at 4; Mot. at 6. Repetition does not improve Plaintiffs' argument, and they have shown by their silence that they cannot dispute this Court's ruling or its commonsense implications.

is necessary to lead to a risk of developing AML – and simply characterizing test results as "high" does not make it so. *See id.*

Plaintiffs' Opposition does nothing to change the fact that they have not plausibly alleged exposure to benzene at sufficient levels, over a sufficient period of time, to lead to the development of AML (nor, despite multiple citations to medical articles, have they pointed this Court to a standard for what such a level or time period would be beyond "long term" and "high"). Minute levels, measured in parts per million, are not necessarily high, and a plausible duration of exposure measured – at most – in months, is certainly not long.[4] Plaintiffs have shown they cannot plausibly plead a defect that caused Mr. Brief's AML, and thus their NJPLA action must be dismissed.

II. PLAINTIFFS FAIL TO ALLEGE A PLAUSIBLE DEFECT UNDER THE NEW JERSEY PRODUCT LIABILITY ACT.

A. Plaintiffs' Opposition Fails To Demonstrate The Requirements For A Plausible Design Defect Claim.

It is well-established that, to maintain a design defect claim under the NJPLA, it is not sufficient for Plaintiffs to allege that a product *could have been different* or that a product *could have been different by omitting an ingredient. See* Mot. at 11 (citing *LaTouche v. Merck & Co., Inc.*, 2023 WL 3604655, at *3 (D.N.J. May 23, 2023)). Plaintiffs do not challenge this standard, or cite any contrary case law; they simply repeat that Defendant could have "not utilized the propellant," Opp. at 8, which is insufficient to state a claim.

Case law in this district also holds that, to maintain a design defect claim, it is not sufficient to simply claim the availability of an alternative design, without alleging facts to plausibly show the availability and feasibility of that design. *See* Mot. at 11-12 (citing *Hindermyer v. B. Braun*

[4] Setting aside the arguments related to the levels and duration of benzene exposure, Plaintiffs also have not alleged facts to show how the alleged levels of benzene in Mr. Brief's Products could lead to the development of his AML compared to the ambient levels of and exposure to benzene omnipresent in everyday life. *See* Mot. at 8-9.

Med. Inc., 419 F. Supp. 3d 809, 825-26 (D.N.J. 2019)). Plaintiffs point to their conclusory allegation that Defendant could have "used a bag-on-valve technology," Opp. at 9, but they do not identify any facts in support, which is insufficient to state a claim. *See* Mot. at 11-12.

The only new argument Plaintiffs raise is that variability in the test results among products in the Valisure report means there must have been available alternative designs. Opp. at 9. The Valisure report claims testing of samples of spray antiperspirants from the following brands: Arrid, Axe, Brut, Degree, Dove, Equate, Old Spice, Right Guard, Secret, Soft & Dri, Suave, and Sure. *See* Request for Judicial Notice ("RJN"), ECF No. 40-8 at 12-17 (hereinafter the "Valisure Report"). The Valisure Report asserts that benzene was found in at least one sample of ***all*** of these brands, and thus ***all*** contain a design defect under Plaintiffs' theory. *See id.* The Valisure Report thus provides no factual basis to support an available alternative design.

Plaintiffs have alleged no facts to support their allegation that there was an available alternative design and as such their NJPLA claim based on design defect must be dismissed.[5]

B. Plaintiffs Cannot State A Failure-To-Warn Claim Because They Plead No Facts to Plausibly Show Deliberate Concealment Or Non-Disclosure Of After-Acquired Knowledge.

Plaintiffs concede that, for a drug regulated by the FDA, they must present clear and convincing evidence that Defendant knew or should have known based upon newly acquired information, of a link between use of the Products and a clinically significant hazard. Opp. at 10. The Court previously dismissed Plaintiffs' NJPLA claim based on alleged failure to warn because "Plaintiffs have not pled *any* facts to demonstrate that 'deliberate concealment or non-disclosure

[5] While Plaintiffs generally request leave to amend, their failure to plausibly allege causation is fatal to all of their claims, so any further amendment would be futile. *See A&E Harbor Transp., Inc. v. Tri-Coastal Design Grp., Inc.*, 2021 WL 1840039, at *1 (D.N.J. May 7, 2021) ("Dismissal of a count in a complaint with prejudice is appropriate if amendment would be inequitable or futile.").

of after-acquired knowledge of harmful effects' rendered any FDA compliant warnings inadequate." ECF No. 30 at 7; *see also Vicente v. Johnson & Johnson*, 2020 WL 7586907, at *13 (D.N.J. Dec. 21, 2020).

In their Opposition, Plaintiffs rely on just two allegations from their SAC to argue this standard is satisfied: (1) "that Valisure issued their Citizen Petition on Benzene in Body Sprays in November 3, 2021," and (2) the issuance of "the Company's February 16, 2022 recall notice." Opp. at 11-12. Their reliance on the second of these allegations is paradoxical: Plaintiffs argue that a recall – a warning – was somehow a ***failure*** to warn. *See id.* Reading these allegations together, approximately three months after publication of the earliest plausible constructive knowledge of the potential presence of benzene in the Products,[6] Defendant initiated a voluntary recall of all lots of the Products in the marketplace in "an abundance of caution" and despite the fact that "no reports of adverse events related to this recall have been reported." RJN, ECF No. 40-4 at 2. This subsequent remedial measure evidences corporate responsibility, not corporate liability – and does not come close to rebutting the "super-presumption" that the FDA-required labeling was adequate. *Kendall v. Hoffman-La Roche, Inc.*, 36 A.3d 541, 554-55 (N.J. 2012) (noting that the presumption in failure-to-warn cases regarding FDA-approved drugs "can be denominated as a super-presumption: absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims; only in the rare case will damages be assessed against a manufacturer issuing FDA-approved warnings") (internal quotations omitted).

[6] Plaintiffs' citation of references in the Valisure Report to potential health effects of benzene "as early as 1897," see Opp. at 11, do not plausibly show prior knowledge, because there are no allegations to show that Defendant knew that the Products contained benzene prior to the Valisure Report.

Even if the three month period between the date the Valisure Report was submitted to the FDA and Defendant's recall announcement could be construed as a failure to warn, there are no allegations that alleged use during that three month period could have, let alone did, play any causal role in Mr. Brief's development of AML. *See supra* at 1-4. Plaintiffs thus again fail to state a NJPLA claim based on alleged failure to warn, and the claim should be dismissed with prejudice.

III. A PLEA FOR DISCOVERY DOES NOT STATE A CLAIM FOR PUNITIVE DAMAGES.

To survive a motion to dismiss a punitive damages claim under the NJPLA involving a FDA-approved drug, Plaintiffs must plausibly allege that the product manufacturer knowingly withheld or misrepresented information required to be submitted under the FDA's regulations, in which the information was material and relevant to the alleged harm. *See* Mot. at 14-15; N.J. Stat. Ann § 2A:58C-5(c).

Plaintiffs attempt to meet this standard in their SAC by referencing a putative class action settlement. SAC ¶ 117. Defendant explained in its Motion why the settlement can no more support a punitive damages claim than it can a NJPLA claim. Mot. at 15. Plaintiffs do not dispute this point – and therefore impliedly concede that the putative class action settlement does not support a punitive damages claim. *See O'Neal v. Middletown Twp.*, 2019 WL 77066, at *3 (D.N.J. Jan. 2, 2019) (citing *Hollister v. U.S. Postal Serv.*, 142 F. App'x 576, 577 (3d Cir. 2005) ("Plaintiffs fail to present any substantive argument in opposition to Defendants' argument, and therefore, have conceded the point.").[7]

Plaintiffs instead focus on two allegations to support their punitive damages claim: (1) the "a little over three months" between the date of the Valisure Report and the issuance of the

[7] Plaintiffs also do not dispute that costs of suit are not recoverable in a NJPLA action and thereby impliedly concede that point as well. Mot. at 14; *see generally* Opp.

voluntary recall announcement; and (2) that the scope of the recall encompassed products that were not included in the Valisure Report. Opp. at 12-13.

The Court has already held that it "will not consider a recall as an admission of a defect particularly where it is part of a putative class action settlement." ECF No. 30 at 4. If a recall cannot be used as evidence that an alleged defect exists, then axiomatically the recall cannot be used to plausibly show that Defendant had knowledge of such defect (or that Defendant withheld that knowledge). Moreover, there can be no plausible inference that "a little over three months" is an unreasonable period of time to initiate a product recall "out of an abundance of caution." *See* Opp. at 12; ECF No. 40-4 at 2. Plaintiffs do not even contend that any purported three-month delay in issuing the recall played any role in Mr. Brief's development of AML; to the contrary, Plaintiffs rely on alleged decades of exposure, making any claim of a delayed recall flatly irrelevant and insufficient to maintain a punitive damages claim under the NJPLA. *See* Mot. at 6; ECF No. 34-1 at 1-2.

As a fall back, Plaintiffs argue that their punitive damages claim should not be dismissed because "discovery has not commenced and no formal discovery has been exchanged between the parties." Opp. at 12. That is an overt fishing expedition – and it is not the law. This Court previously rejected "Plaintiffs' repeated assertion that it is premature to resolve any legal issues without the benefit of discovery" because "[a] motion to dismiss, by express rule and design, must be made before a responsive pleading and discovery." ECF No. 30 at 3.

Having now repeatedly demonstrated their inability to state a plausible basis for punitive damages under the NJPLA, their claim should be dismissed with prejudice.

CONCLUSION

For the reasons set forth above and those in its Motion to Dismiss, Defendant respectfully requests that the Court grant its Motion to Dismiss and dismiss Plaintiffs' Complaint in its entirety with prejudice.

Dated: August 14, 2023
New York, New York

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